UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

THIS DOCUMENT RELATES TO ALL CASES

CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

ADAM M. SLATER, hereby certify as follows:

- 1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' opposition to Defendants' motion for summary judgment.
- 2. Attached hereto as **Exhibit 126** is a true and accurate copy of ZHP00310309.
- 3. Attached hereto as **Exhibit 127** is a true and accurate copy of ZHP00380568.

- 4. Attached hereto as **Exhibit 128** is a true and accurate copy of ZHP01390017.
- 5. Attached hereto as **Exhibit 129** is a true and accurate copy of ZHP02214647.
- 6. Attached hereto as **Exhibit 130** is a true and accurate copy of ZHP00359796.
- 7. Attached hereto as **Exhibit 131** is a true and accurate copy of PRINSTON00074174.
- 8. Attached hereto as **Exhibit 132** is a true and accurate copy of ZHP01447094.
- 9. Attached hereto as **Exhibit 133** is a true and accurate copy of ZHP01429887.
- 10. Attached hereto as **Exhibit 134** is a true and accurate copy of PRINSTON00147028.
- 11. Attached hereto as **Exhibit 135** is a true and accurate copy of ZHP01870977.
- 12. Attached hereto as **Exhibit 136** is a true and accurate copy of ZHP00021455.
- 13. Attached hereto as **Exhibit 137** is a true and accurate copy of TORRENT-MDL2875-00074133.

- 14. Attached hereto as **Exhibit 138** is a true and accurate copy of the transcript of Dr. Stephen Hecht's January 13, 2023 deposition.
- 15. Attached hereto as **Exhibit 139** is a true and accurate copy of Dr. Stephen Hecht's July 6, 2021 expert report.
- 16. Attached hereto as **Exhibit 140** is a true and accurate copy of *FDA* Statement on the *FDA's* ongoing investigation into valsartan and *ARB* class impurities and the agency's steps to address the root causes of the safety issues (Jan. 25, 2019).
- 17. Attached hereto as **Exhibit 141** is a true and accurate copy of the ICH's Draft Consensus Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (M7).
- 18. Attached hereto as **Exhibit 142** is a true and accurate copy of the EMEA's Guideline on the Limits of Genotoxic Impurities.
- 19. Attached hereto as **Exhibit 143** is a true and accurate copy of the FDA's Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products.
- 20. Attached hereto as **Exhibit 144** is a true and accurate copy of Dr. Stephen Hecht's October 31, 2022 supplemental expert report.

- 21. Attached hereto as **Exhibit 145** is a true and accurate copy of TORRENT-MDL2875-00072713.
- 22. Attached hereto as **Exhibit 146** is a true and accurate copy of PRINSTON00463676.
- 23. Attached hereto as **Exhibit 147** is a true and accurate copy of PRINSTON00463638.
- 24. Attached hereto as **Exhibit 148** is a true and accurate copy of ZHP01890025.
- 25. Attached hereto as **Exhibit 149** is a true and accurate copy of PRINSTON00019518.
- 26. Attached hereto as **Exhibit 150** is a true and accurate copy of PRINSTON00177013.
- 27. Attached hereto as **Exhibit 151** is a true and accurate copy of ZHP02457852.
- 28. Attached hereto as **Exhibit 152** is a true and accurate copy of the "Solco Product List."
- 29. Attached hereto as **Exhibit 153** is a true and accurate copy of PRINSTON00345256.
- 30. Attached hereto as **Exhibit 154** is a true and accurate copy of SOLCO00223261.

- 31. Attached hereto as **Exhibit 155** is a true and accurate copy of Dr. Rena Conti's November 10, 2021 expert declaration.
- 32. Attached hereto as **Exhibit 156** is a true and accurate copy of Dr. Kali Panagos's October 31, 2022 expert report.
- 33. Attached hereto as **Exhibit 157** is a true and accurate copy of PRINSTON0012473.
- 34. Attached hereto as **Exhibit 158** is a true and accurate copy of SOLCO00012088.
- 35. Attached hereto as **Exhibit 159** is a true and accurate copy of SOLCO00189499.
- 36. Attached hereto as **Exhibit 160** is a true and accurate copy of SOLCO00025179.
- 37. Attached hereto as **Exhibit 161** is a true and accurate copy of SOLCO00033300.
- 38. Attached hereto as **Exhibit 162** is a true and accurate copy of SOLCO00181380.
- 39. Attached hereto as **Exhibit 163** is a true and accurate copy of SOLCO00180393.
- 40. Attached hereto as **Exhibit 164** is a true and accurate copy of Dr. Ramin Najafi's January 18, 2023 deposition.

- 41. Attached hereto as **Exhibit 165** is a true and accurate copy of Dr. Ramin Najafi's February 3, 2022 deposition.
- 42. Attached hereto as **Exhibit 166** is a true and accurate copy of Dr. Ramin Najafi's October 31, 2022 expert report.
- 43. Attached hereto as **Exhibit 167** is a true and accurate copy of the USP's <1086> Impurities in Drug Substances and Drug Products.
- 44. Attached hereto as **Exhibit 168** is a true and accurate copy of PRINSTON00085351.

MAZIE SLATER KATZ & FREEMAN, LLC Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: January 22, 2024